SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbolan Lactating 200 mg intramammary suspension for cattle and sheep [UK]
Orbenin Lactation 200 mg intramammary suspension for cattle and sheep [NL]
Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep [DE, ES, PT]
Orbelux LA 200mg intramammary suspension for cattle and sheep [PL]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g dose unit contains the following:

Active substance:
Cloxacillin as cloxacillin sodium 200 mg

Excipient:
Butylhydroxyanisole (E 320) 0.558 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension.
An off-white viscous suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating cows) and sheep (sheep for meat production)

4.2 Indications for use, specifying the target species

Lactating cows
For the treatment of mastitis associated with staphylococcal and streptococcal species sensitive to cloxacillin.

Ewes
For the treatment of subclinical infections of the udder during the dry period, associated with staphylococcal species and *Trueperella pyogenes* sensitive to cloxacillin.

4.3 Contraindications

Do not use in animals with known hypersensitivity to cloxacillin, other β-lactam antibiotics or to any of the excipients.

4.4 Special warnings for each target species

For the best results in cattle, the product should be used at the earliest signs of infection.

In staphylococcal and certain forms of streptococcal mastitis, an adequate duration of treatment is important in achieving both clinical and bacteriological cures.

4.5 Special precautions for use

Special precautions for use in animals

Individual syringes must only be used once.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the cloxacillin and may decrease the effectiveness of the treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases ß-lactam antibiotics may cause hypersensitivity reactions (allergic skin reactions, anaphylaxis). If such a reaction occurs, the current treatment should be stopped immediately and an appropriate symptomatic treatment be initiated.

4.7 Use during pregnancy, lactation or lay

The product is indicated for use in the lactating cow and for use in ewes at weaning.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intramammary use.

Cows
Dosage
The recommended dose is three infusions per infected quarter - one syringe administered every 48 hours.
Dosing guide
Clean and disinfect the teat with the cleaning towel provided or surgical spirit after milking; insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed. The treated quarter(s) may be milked out at the next normal milking time.

Ewes
Dosage
A single infusion should be made into each udder half at weaning.
Administration
It is important that a simple hygienic procedure is followed. One operator should turn up and hold each ewe whilst a second person carries out the infusion technique. Clean and disinfect each teat end thoroughly with the cleaning towel provided or surgical spirit. Appose the syringe nozzle to the teat orifice and apply gentle, continuous pressure to express the suspension in the udder. Actual cannulation of the teat orifice is neither necessary nor desirable. Use a fresh syringe for each udder half to avoid the possibility of cross contamination during infusion.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Cattle - milk: 96 hours
Not authorised for use in sheep producing milk for human consumption
Cattle and sheep - meat and offal: 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: beta-lactam antibacterials, penicillins, for intramammary use
ATCvet code: QJ51CF02

5.1 Pharmacodynamic properties

Cloxacillin, a semi-synthetic β-lactam antibiotic, is active against Gram-positive organisms, but is not destroyed by staphylococcal penicillinase. It is therefore active against penicillin resistant staphylococci which are an important cause of mastitis. The antibiotic is bactericidal at the concentrations produced in the udder.

5.2 Pharmacokinetic particulars

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E 320)
Castor Oil, Hydrogenated
Silica, Hydrophobic Colloidal
Arachis Oil, Refined

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25 °C
Store in a dry place.

6.5 Nature and composition of immediate packaging

Low density polyethylene (LDPE) intramammary syringe comprising dual nozzle, barrel and cap.
Pack size:
12 intramammary syringes and cleaning towels per carton.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4188

9. DATE OF FIRST AUTHORISATION

14 October 2015

10. DATE OF REVISION OF THE TEXT

November 2019

Approved: